



**Livestock and Seed Program  
Audit, Review, and Compliance Branch  
Quality System Audit Report**

**AUDIT INFORMATION**

<b>Applicant Name:</b>	Istituto Mediterraneo Di, Certificazione s.r.l. (IMC)
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<b>Auditor(s):</b>	Darrell Wilson
<b>Program:</b>	USDA National Organic Program (NOP)
<b>Audit Date(s):</b>	December 07, 2006
<b>Audit Identifier:</b>	NP6254OOA
<b>Action Required:</b>	Yes
<b>Audit Type:</b>	Corrective Action Audit
<b>Audit Objective:</b>	To verify that corrective actions adequately address the non-compliances identified during the 2006 Annual Update audit and on-site surveillance audit.
<b>Audit Criteria:</b>	7 CFR Part 205, National Organic Program, Final Rule, dated December 21, 2000; updated September 11, 2006
<b>Audit Scope:</b>	IMC's submitted corrective actions
<b>Location(s) Audited:</b>	Desk

**FINDINGS**

IMC submitted corrective actions on November 29, 2006, to address the non-compliances issued during the 2006 Annual Update audit and on-site surveillance audit. The information submitted was sufficient to clear one non-compliance and adequately address one non-compliance. Five non-compliances were not adequately addressed and remain outstanding.

**NP6233OOA.NC1 –Minor – Cleared** – NOP §205.510 (a)(1) requires, “An accredited certifying agent must submit annually to the Administrator...A complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504.” §205.504 (c)(2) requires A conflict of interest disclosure report for all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent. The report must identify any food- or agriculture-related business interests, including business interests of immediate



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family members that cause a conflict of interest. *Conflicts of Interest Disclosure statements were not included with the 2006 Annual Update submission.* **Corrective Action:** IMC has indicated that a wrong interpretation of the NOP standards was made and that arrangements will be made to have them signed annually. Conflict of interest disclosure statements were reviewed during the onsite audit (NP6254OOA).

**NP6254OOA.NC1 - Major – Not Adequately Addressed** – NOP §205.501 (a) states, “A private or governmental entity accredited as a certifying agent under this subpart must: (11) Prevent conflicts of interest by: (v) Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.” *Although most personnel complete a contract that provides for conflict of interest; however, the contracts are not renewed annually, and they contain only the declaration that the person has no conflicts. One Certification Committee member provides consulting work for a company certified by IMC for the EU regulation. The minutes for the meeting that decided the certification for the company indicated the involved member did not participate in the decision process for that particular company. This element was identified during the annual update review for the 2004 and 2005 submission and remains outstanding.* **Corrective Action:** IMC indicates that they will be acquiring a complete declaration of conflicts annually. Since this section requires a procedure, a procedure indicating annual signing of conflict of interest disclosures will need to be provided for review before this non-compliance can be adequately addressed.

**NP6254OOA.NC2 – Minor – Not Adequately Addressed** – NOP § 205.201 states, “(a) The producer or handler of a production or handling operation... must develop an organic production or handling system plan... An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include: 1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed; 2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable; 3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented; 4) A description of the recordkeeping system implemented to comply with the requirements established in 205.103; 5) A description of the management practices and physical barriers established to prevent commingling of organic and non-organic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and 6) Additional information deemed necessary by the certifying agent to evaluate compliances with the regulation.” *The organic production and handling system plans do not contain the information necessary as required in this section.* **Corrective Action:** IMC indicates that the production and handling system plans will be updated to include the missing information. Copies of the revised production and handling system plans will need to be provided for review before this non-compliance can be adequately addressed.



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**NP6254OOA.NC3 – Minor – Adequately Addressed** – NOP § 205.403 (c)(1) states, “Verification of information. The on-site inspection of an operation must verify: The operation’s compliance or capability to comply with the regulations in this part.” *During the on-site witness audit for the production operation, the inspector recorded “not applicable” to sections of the checklist that verified information concerning storage of seed and fertilizers. The sections concerning the equipment maintenance, storage and organic use was not verified on the inspection report. This operation is part of a cooperative where all of the seed and equipment storage is shared between three operations owned by brothers, and all storage and maintenance is done on one of the other operations reviewed by the same inspector.*

**Corrective Action:** IMC has formally warned the auditor about this situation and has asked for additional information concerning this operation.

**NP6254OOA.NC4 – Minor – Not Adequately Addressed** – NOP § 205.404 (a) states, “...If the certifying agent determines that the organic system plan and all procedures and activities of the applicant’s operation are in compliance...the agent shall grant certification. b) The certifying agent must issue a certificate of organic operation which specifies the: 2) Effective date of certification.” *Updated certificates do not contain the effective date of certification. The dates indicated on the certificates are the updated dates.* **Corrective Action:** IMC will be setting up a compliance certificate form which will include the date of first issue and revision dates add as necessary. An example of this document will need to be provided before this non-compliance can be adequately addressed.

**NP6254OOA.NC5 - Minor – Not Adequately Addressed** – NOP § 205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges it has filed with the Administrator... The certifying agent may set the nonrefundable portion of the certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator.” *The interview with the Quality Manager indicated discounts may be given to clients on a case by case basis. These discounts are not detailed in the fee schedule submitted to the Administrator. IMC’s fee schedule submitted to the Administrator does not provide information concerning the portion of certification fees that are refundable.* **Corrective Action:** IMC indicates that the missed information will be added to the Regulation-table of fees. The revised schedule will need to be provided before this non-compliance can be adequately addressed.

**NP6254OOA.NC6 – Minor – Not Adequately Addressed** – NOP § 205.662 (d) states, “Willful violations. Notwithstanding paragraph (a) of this section, if a certifying agent...has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent...shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the non-compliance.” *A letter of proposed revocation that meets the requirements of 205.662 (c) was not sent to Bio-Nile prior to sending the notice of revocation.* **Corrective Action:** IMC indicated that the NOP standards had been wrongly translated. Corrections are to be made to correct this issue. Revised documents will need to be provided before this non-compliance can be adequately addressed.